

AP20 Rec'd PCT/PTO 28 JUL 2006  
IN THE EUROPEAN PATENT OFFICE

PATENT COOPERATION TREATY  
International Preliminary Examining Authority  
Attention: A. Borowski

In re International Application of: THE GOVERNMENT OF THE UNITED STATES OF  
AMERICA AS REPRESENTED BY THE SECRETARY  
OF THE DEPARTMENT OF HEALTH AND HUMAN  
SERVICES, CENTERS FOR DISEASE CONTROL AND  
PREVENTION, et al.

International Application No.: PCT/US2005/011086

International Filing Date: 01 April 2005 (01.04.2005)

For: AEROSOL DELIVERY SYSTEMS AND METHODS

Date: June 7, 2006

#### RESPONSE TO WRITTEN OPINION

European Patent Office  
Erhardstrasse 27  
D-80331 Munich  
GERMANY

Via Facsimile No. 011 49 89 2399 4465  
Confirmation via DHL No. 776 2891 710

Dear Officer Borowski:

In response to the Written Opinion of the International Searching Authority mailed on 8 March 2006, replacement pages 29 through 36, including amendments to claims 1, 6, 11, and 46, are enclosed for consideration during preliminary examination under Article 34. Please replace pages 29 through 35 of the international application with the attached replacement pages 29 through 36. In the attached replacement pages, claims 1, 6, 11, and 46 are amended, new claims 59-63 are added, and the remaining claims are unchanged.

The Written Opinion of the International Searching Authority (Opinion) contends that D1 discloses the features recited in claim 1. Claim 1 has been amended to further recite: "projections disposed in the chamber and maintaining a minimum spacing between the movable element and the orifices, the projections being configured to contact the inner surface of the movable element and an opposing inner surface of the chamber defining said orifices to maintain the minimum spacing when the external force is applied to the exterior surface."

In contrast to claim 1, D1 discloses a spray device 5 comprising a top substrate 18 and a bottom substrate 8, with pyramid-shaped cavities 13 etched in the top substrate 18 and a respective outlet nozzle 14 above each cavity 13 (see FIGS. 2-4). The pyramid-shaped cavities 13 are formed by etching recesses in the lower surface of the top substrate 18 at

selected spaced-apart locations. Although not shown in the drawings of D1, as D1 is presently understood, the portion of the top substrate surrounding the cavities 13 is a continuous web of material (when viewed from the bottom, the cavities 13 are completely surrounded by material forming the top substrate). Hence, the top substrate does not form a plurality of discrete projections in the chamber. Further, even assuming for purposes of discussion that the top substrate forms a plurality of projections, D1, as presently understood, is silent as to whether those portions of the top substrate 18 surrounding the cavities are capable of contacting the bottom substrate in use to maintain a minimum spacing in the chamber, in contrast to the projections recited in claim 1.

In the instantly claimed device, agent is allowed to flow around the projections and through the chamber when the projections come in contact with the opposing surface of the chamber. If projections are not provided and the moveable element is allowed to contact the orifice plate, flow of agent through the chamber may be restricted, thereby starving the orifices of agent and resulting in decreased output from the device. By maintaining flow into and through the chamber by use of the projections, the flow of agent through the chamber is optimized so as to optimize the output of the device. In D1, if the bottom substrate 8 is allowed to contact the lower surface of the top substrate 18, the contact between the two opposing surfaces would prevent agent from flowing through the chamber 9 and between the recesses 13. This could restrict flow of agent through the chamber 9 and starve cavities 13 of the agent, and therefore reduce the output of the device. Thus, D1 inherently does not teach or suggest a device capable of maintaining a minimum spacing in the fluid chamber without restricting the flow of agent to be aerosolized, as in Applicants' device.

Accordingly, for at least the foregoing reasons, claim 1 is patentable over D1. Neither D2 nor D3 teaches or suggests an aerosolizing element comprising a chamber and a plurality of projections disposed in the chamber, and therefore these references do not make up for the deficiencies of D1. Applicants note that the limitation "projections disposed in the chamber and maintaining a minimum spacing between the moveable element and the orifices" was previously recited in original claim 11. The International Search Report did not cite D2 or D3 as being relevant to original claim 11.

Claims 2-25 depend from claim 1 and recite respective combination of features that are independently patentable over D1-D3.

For example, amended claim 8, in combination with claim 7, further recites an orifice plate defining the orifices, the orifice plate consisting essentially of a metal foil. By forming the orifice plate from a thin metal foil, the orifice plate is allowed to flex when the moveable element is excited to expel agent through the orifices. Advantageously, allowing the orifice plate to flex during use maximizes throughput of the device. D1, in contrast,

states that the top substrate 18 comprises a main body portion consisting of plastic, high density polymer, ceramics, metal, or silicon and a nozzle body made of silicon. Due to the silicon nozzle body, the construction of the top substrate 18 in D1 is understood to result in a relatively rigid, non-flexible structure.

Claim 11 has been amended to recite that the projections are dimensioned to contact the inner surface of the movable element and the opposing inner surface of the chamber when the external force is not applied to the moveable element. In contrast, as clearly shown in FIGS. 2-4 of D1, the bottom substrate 8 cannot contact the lower surface of the top substrate 18 when the bottom substrate is not deflected by the actuator.

Claim 18 further recites that the chamber includes an air vent separate from the inlet. The structure disclosed in D1 does not include an air vent, nor does D1 provide any hint or suggestion for implementing an air vent in the device.

Claim 20 further recites at least one airflow passageway extending through the body such that air flowing through the passageway can carry the expelled agent away from the element. Upon ejection from the orifices, aerosol droplets can be immediately entrained by the air flowing outwardly from the airflow passageway to facilitate delivery of the agent to the patient. In contrast, there clearly is no provision in D1 for an airflow passageway extending through the body of the device 5 (see FIGS. 2-4). In fact, D1 teaches placing a "boosting means" between the outlet nozzles 14 and the mouthpiece 6 to facilitate delivery of agent to the patient. See paragraph 55. In this manner, D1 teaches against providing an airflow passageway through the device 5 because the boosting means is placed downstream of the device 5.

Claim 21, in combination with claim 20, further recites that the airflow passageway comprises an inlet defined in one side of the body and an outlet defined in an opposing side of the body, the outlet being offset from the inlet. This configuration is advantageous in that it protects against expired particles from the patient from flowing back through the passageway and contacting the re-useable parts of the delivery device. D1 fails to provide any hint or suggestion for this configuration.

Claim 22 further recites that the body comprises first and second reflective surfaces positioned on opposite sides of the orifices such that a light beam passing through the element is reflected by the first reflective surface to extend in front of the orifices and onto the second reflective surface, which reflects the light beam back through the element. The reflective surfaces allows the device to be used with an aerosolization rate monitor comprising a light source that projects a light beam across the orifices for monitoring the aerosolization rate. Again, D1 fails to provide any hint or suggestion for the specific configuration recited in claim 22.

Claim 23, in combination with claim 3, recites that the moveable element comprises a flexible diaphragm, which comprises a plurality of projections that maintain a minimum chamber thickness. In contrast, FIGS. 2-4 of D1 clearly show that the upper surface of the moveable bottom substrate 8 is flat and is not formed with any projections.

New claims 59-63 have been added to recite further details of the device. Claim 63, for example, recites the aerosolizing element of claim 1 in combination with the aerosol delivery device wherein the aerosol delivery device comprises an ultrasonic horn coupled to the moveable element. An ultrasonic horn utilizes an actuator (e.g., a piezoelectric actuator) and a motion transmitting member coupling the actuator to the moveable element of the aerosolizing element (as best shown in FIG. 4B). The motion transmitting member shown in FIG. 4B provides the advantage of increasing the amplitude of the vibrations transferred to the moveable element to optimize the output of the device. In contrast, D1 expressly teaches connecting an actuator 10 directly to the moveable bottom substrate 8 without a motion transmitting member for amplifying the vibrations of the actuator.

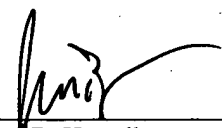
**Please notify the undersigned immediately by telephone or facsimile if any additional information is required.**

Respectfully submitted,

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cc: Docketing